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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,525	11/01/2005	David Dakin Iorwerth Wright	07588.0080	7399

22852 7590 07/05/2007
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EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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07/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,525

Applicant(s)

WRIGHT ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8,9,12-16,18-29,31,64-66,69-71,73-76 and 78-82 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8,9,12-15,18-20,24-29,31,64-66,69-71,73,74,76,78,79,81 and 82 is/are rejected.
- 7) ☒ Claim(s) 16,21-23,75 and 80 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on January 26, 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1, 4, 5, 8, 9, 12-16, 18-29, 31, 64-66, 69-71, 73-76 and 78-82 are pending.

Drawings

1. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

Claim Objections

2. Claims 28 and 71 are objected to because of the following informalities: claim 28 is directed to a method of claim 25; however, claim 25 is directed to a composition.

Claim 71 is missing a period at the end of the claim. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 4, 5, 8, 9, 12-14 and 18-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-17 of copending application No. 10/522,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a foam comprising a liquid phase containing at least one sclerosing agent and a gas phase comprising at least one physiologically acceptable gas. The difference between the two is the instant invention contains a viscosity-enhancing agent. The addition of a viscosity enhancing would have been obvious to one of ordinary skill in the art as a means to formulate the foam in a consistency that would achieve the claimed density and half-life of the foam.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1, 8, 18-20 and 24-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 10, 11, 12, 14 and 21 of copending application No. 10/890,267. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a foam comprising a liquid phase containing at least one sclerosing agent and a gas phase comprising at least one physiologically acceptable gas. The difference between the two is the instant invention contains a

viscosity-enhancing agent. The addition of a viscosity enhancing would have been obvious to one of ordinary skill in the art as a means to formulate the foam in a consistency that would achieve the claimed density and half-life of the foam.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1, 8, 9, 18-20, 26-28, 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-18, 33 and 35-40 of copending application No. 11/128,265. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a foam comprising a liquid phase containing at least one sclerosing agent and a gas phase comprising at least one physiologically acceptable gas. The difference between the two is the instant invention contains a viscosity-enhancing agent. The addition of a viscosity enhancing would have been obvious to one of ordinary skill in the art as a means to formulate the foam in a consistency that would achieve the claimed density and half-life of the foam.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 64-66, 69-71, 73, 74, 76, 78, 79 and 82 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 68, 69, 71, 72, 74-76, 80-82, 87, 88, 91-94, 96, 97, 100-102 and 107 of

compending application No. 11/171,293. Although the conflicting claims are not identical, they are not patentably distinct from each other because both compending applications are directed to a method of producing a foam comprising passing a mixture of at least one sclerosing agent and at least one physiologically acceptable gas through a passage. The difference between the two is the cross-sectional dimensions of the passages as claimed in the instant invention. The determination of the cross-sectional dimensions would have been obvious to one of ordinary skill in the art as a means to formulate the foam in a consistency that would achieve the desired results of the claimed foam.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 64 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of compending application No. 11/225,860. Although the conflicting claims are not identical, they are not patentably distinct from each other because both compending applications are directed to a method of producing a foam comprising passing a mixture of at least one sclerosing agent and at least one physiologically acceptable gas through a passage having a cross-sectional dimension of from 0.1 to 30 microns, a density of between 0.07 g/mL to 0.19 g/mL and a half-life of at least 2 minutes. The difference between the compending applications is the ranges of the cross-sectional passages, density and half-life. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie

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case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 64-66, 69, 70, 78, 79, 81 and 82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 7, 18 and 19 of U.S. Patent No. 6,572,873. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a method of producing a foam comprising passing a mixture of at least one sclerosing agent and at least one physiologically acceptable gas through a passage having a cross-sectional dimension of from 0.1 to 30 microns, a density of between 0.07 g/mL to 0.19 g/mL and a half-life of at least 2 minutes and wherein the foam has at least 50% by number gas bubbles with a 25 micron diameter and above are no more 200 microns. The difference between the instant invention and the patent are the ranges of the cross-sectional passages, density and half-life. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

9. Claims 64-66, 69, 70, 78, 79 and 82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 7 and 8 of

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U.S. Patent No. 7,025,290. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applications are directed to a method of producing a foam comprising passing a mixture of at least one sclerosing agent and at least one physiologically acceptable gas through a passage having a cross-sectional dimension of from 0.1 to 30 microns, a density of between 0.07 g/mL to 0.19 g/mL and a half-life of at least 2 minutes. The difference between the instant invention and the patent are the ranges of the cross-sectional passages, density and half-life. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
10. Claims 1, 13, 15, 18, 19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabrera Garrido et al. (US 5,676,962).

Determination of the scope and content of the prior art

(MPEP §2141.01)

Cabrera Garrido et al. teach in example 1 a microfoam preparation comprising a sclerosing agent in a bottle under oxygen pressure, together with a mixture of oxygen and carbon or other physiological gases. It is also taught that if the agent doesn't have a foaming capacity, Polysorbate 20 can be used. Column 2, lines 16-21 teach examples of the agent such as polydocanol, sodium tetradecylsulfate, etc.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

Cabrera Garrido et al. do not teach the concentration of the viscosity agent or the physiological gas.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

The determination of the concentrations of the viscosity agent and of the physiological gas would have been obvious to one of ordinary skill in the art at the time

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of the invention as part of normal experimentation to achieve the desired foam consistency.

Allowable Subject Matter

11. Claims 16, 21-23, 75 and 80 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a foam comprising a liquid phase comprising one sclerosing agent and at least 20% vol/vol of at least one viscosity enhancing agent and a gas phase composition at least 50% of CO₂, wherein the liquid phase further comprises water and/or saline (claims 21-23) or wherein the viscosity enhancing agent is chosen from glycerol or PVP (claim 16). The prior art also does not teach a method of producing the foam as taught in claim 64 together with a viscosity-enhancing agent (claims 75 and 80). The closest prior art reference of Cabrera Garrido et al. do not teach, disclose or suggest those limitations.

Conclusion

12. Claims 1, 4, 5, 8, 9, 12-15, 18-20, 24-29, 31, 64-66, 69-71, 73, 74, 76, 78, 79, 81 and 82 are rejected.


Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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